REMARKS

Interview request

Applicants also respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative at 858 720 5133.

Status of the Claims

Pending claims

Claims 1 to 3, 6, 11 to 12, 20 to 22 and 50 to 68 are pending. Claims 3 and 6 are withdrawn from consideration. Thus, claims 1, 2, 11 to 12, 20 to 22 and 50 to 68 are pending and under consideration – with the caveat that new claims 65 and 68 are, in part, drawn to non-elected subject matter (see page 2, lines 16 to 19, of the OA).

Claims added in this response

Claims 69 to 73 are added; thus, after entry of this amendment, claims 1 to 3, 6, 11 to 12, 20 to 22 and 50 to 73 will be pending.

Outstanding Objections and Rejections

Claims 1, 50, 53 to 64 and 67 are objected to. Claims 1, 2, 11, 12, 20 to 22 and 50 to 68, were rejected under 35 U.S.C. § 112, second paragraph. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 112, first paragraph, written description requirement. Claims 1, 2, 20 to 22, 51, and 53 to 62 were rejected under 35 U.S.C. § 112, first paragraph, enablement requirement. Claims 1, 2, 20 to 22, 51, and 53 to 62 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Berka *et al.*, U.S. Patent No. 5,866,118. Claims 1, 2, 11, 12, 20 to 22, 51, 53 to 62 and 66, are newly rejected as allegedly unpatentable over Ostanin, et al., (1992) J. Biol. Chem. 267(32):22830-22836 (hereafter "Ostanin") in view of Berka.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the Claim Amendments

The specification sets forth an extensive description of the invention in the new and amended claims. For example, support for claims directed to methods of expressing phytases comprising a homologous signal sequence or comprising a heterologous signal sequence in place of the homologous signal sequence, and in one aspect, comprising a sequence imparting a desired characteristic, can be found, inter alia, in paragraphs [0254], [0315] and [0316] of U.S. Patent Application Publication No. 20040091968 ("the '968 publication"). Accordingly, Applicants respectfully submit that no new matter is introduced by the instant amendment.

The Group Restriction Requirement, Election and Traversal

The Patent Office alleged that the pending claims of the application are directed to six separate and distinct inventions under 35 U.S.C. §121. In their last response of October 27, 2006, Applicants elected Group IV, drawn to, *inter alia* methods of recombinantly producing the polypeptide of SEQ ID NO:10, with traverse.

In their October, 2006, response Applicants respectfully requested the Patent Office reconsider and, in part, withdraw the group restriction requirement. In brief, Applicants respectfully submitted that all exemplary phytases sequences, including the phytase encoding nucleic acids SEQ ID NO:1 and SEQ ID NO:9, and the phytases SEQ ID NO:2 and SEQ ID NO:10, should be rejoined to a generic Group IV; in other words, Groups III and IV should be joined to a generic group drawn to methods for making a polypeptide having a phytase activity comprising, inter alia, expressing a phytase-encoding nucleic acid in a yeast. Thus, pursuant to 37 C.F.R. § 1.144, Applicants reserved the right to petition for review of the restriction requirement at any time prior to appeal.

Applicants thank the Examiner for acknowledging that claims 1 and 2 are generic linking claims and that Applicants are entitled to examination of these generic claims, and that the restriction requirement between the linked inventions is subject to the non-allowance of the linking claims 1, 2 and 51, see pages 2 to 3 of the OA.

Claim Objections

Claims 1, 50, 53 to 64 and 67 are objected to for reasons set forth in paragraphs 4 to 9, pages 3 to 4, of the OA. The instant amendment addresses this issue.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claim 1, 2, 11, 12, 20 to 22 and 50 to 68, were rejected under 35 U.S.C. § 112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as discussed in paragraphs 10 to 13, on pages 4 to 6, of the OA. The instant amendment addresses this issue.

Rejection Under 35 U.S.C. § 112, First Paragraph, Written Description

The rejection of claims 1, 2, 20 to 22, 51, and 53 to 62 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, is maintained for reasons set forth in paragraphs 17 to 20, pages 6 to 8, of the OA.

Nucleic acids isolated from a wild type E. coli bacterium

Applicants respectfully aver that the skilled artisan would have understood the inventor to be in possession of the claimed invention with regards to "nucleic acids isolated from a wild type *E. coli* bacterium" at the time of filing.

However, it appears that the Office is not questioning whether "nucleic acids isolated from a wild type *E. coli* bacterium" are sufficiently described in the specification. The Office is concerned that the pending wording of the claims might read on recombinant expression of any phytases – not just "nucleic acids isolated from a wild type *E. coli* bacterium". For example, "nucleic acids isolated from a recombinant *E. coli* bacterium" might encompass any phytase (see, e.g., lines 5 to 8, of paragraph 20, page 7, of the OA).

The instant amendment addresses this issue, thus satisfying the Examiner's concerns. The instant amendment clarifies that the claimed methods of the invention only recombinantly express "nucleic acids isolated from a wild type *E. coli* bacterium", or non-natural or synthetic forms

thereof, or the novel phytase SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9) first described in this invention.

Expressing the nucleic acid in a yeast

Additionally, to clarify a point: while the Office alleged that claims 11 and 12 encompass the same genus of nucleic acids required by the method of claim 1, in fact, claims 11 and 12 only expressly enumerate exemplary yeast cells that can be used to express the nucleic acids isolated from a wild type *E. coli* bacterium, or non-natural or synthetic forms thereof, or the novel phytase of this invention SEQ ID NO:10 ("...expressing the nucleic acid in a yeast ...):

> Claim 11 (previously presented): The method of claim 1, wherein the yeast cell is a *Saccharomyces* sp., a *Schwanniomyces* sp., a *Pichia* sp. yeast cell, a *Hansenula* sp. yeast cell, a *Candida* yeast cell or a *Torulopsis* sp. yeast cell.
>
> Claim 12 (original): The method of claim 11, wherein the yeast cell is a *Saccharomyces cerevisiae*, a *Schizosaccharomyces pombe*, a *Schwanniomyces occidentalis*, a *Pichia pastoris* or a *Hansenula polymorpha*.

Thus, claims 11 and 12 do not further limit any of the nucleic acids used in the method of claim 1, they only limit the scope of what particular yeast cells those nucleic acids are inserted into for recombinant expression.

SEQ ID NO:1/2 is a wild-type E. coli B phytase and SEQ ID NO:9/10 is man-made

To clarify another point: the Office alleged that the phytases of SEQ ID NO:2 and SEQ ID NO:10 are man-made; however, the phytase SEQ ID NO:2 (encoded e.g., by SEQ ID NO:1) is a wild-type *E. coli* B phytase and SEQ ID NO:10 is a "man-made" phytase of this invention (created from – whose parent sequence is – the *E. coli* K12 phytase SEQ ID NO:8, encoded e.g., by SEQ ID NO:7). Please see, inter alia, paragraphs 0066 and 0067, of the '968 publication:

> [0066] FIGS. 7a and 7b shows the nucleotide sequence of E. coli appA phytase (SEQ ID NO:7).
> [0067] FIG. 8 shows the amino acid sequence of E. coli appA phytase (SEQ ID NO:8) and a modified phytase (SEQ ID NO:10). [emphasis added]

See also paragraph 0057, of the '968 publication:

[0057] The invention also provides phytase encoding polynucleotides having a nucleotide sequence substantially identical to SEQ ID NO:7, and having a modified nucleotide sequence selected from nucleotide 389 is G; 390 is A; nucleotide 437 is T; 438 is G; 439 is G; 470 is C; 472 is T; 476 is T; 477 is G; 478 is T; 689 is G; 690 is A; 691 is G; 728 is T; 729 is A; 730 is T; 863 is T; 864 is G; 1016 is G, or any combination thereof. Further, the invention provides a polynucleotide having a nucleotide sequence substantially identical to SEQ ID NO:7, and having a modified nucleotide sequence selected from nucleotide 389 is G and 390 is A (SEQ ID NO:5); nucleotide 437 is T, 438 is G and 439 is G (SEQ ID NO:6); 470 is C and 472 is T; 476 is T, 477 is G, and 478 is T; 689 is G, 690 is A and 691 is G; 728 is T, 729 is A, and 730 is T; 863 is T and 864 is G; 1016 is G, or any combination thereof. The later sequence is exemplified in SEQ ID NO:9 and the corresponding amino acid sequence is SEQ ID NO:10. [emphasis added]

See also paragraphs 0269 and 0271, of the '968 publication:

[0269] For convenience of discussion and for use as a frame of reference, the phytase nucleotide sequence set forth in SEQ ID NO:1 or SEQ ID NO:7 is referred to as a "wild type" polynucleotide or "wild type" gene sequence, and, similarly, the polypeptide set forth as SEQ ID NO:2 or SEQ ID NO:8 is referred to as a wild type phytase polypeptide. [emphasis added]

[0270] Examples of a variant phytase polynucleotide sequence include sequences substantially as set forth in SEQ ID NO:7, wherein the polynucleotide has a nucleotide sequence as set forth in a) SEQ ID NO:9; b) SEQ ID NO:9 wherein all Ts are Us (RNA); wherein the expression of the phytase-encoding nucleic acid leads to the production of said substantially pure phytase enzyme; and c) SEQ ID NO:7, wherein 389 is G; 390 is A; nucleotide 437 is T; 438 is G; 439 is G; 470 is C; 472 is T; 476 is T; 477 is G; 478 is T; 689 is G; 690 is A; 691 is G; 728 is T; 729 is A; 730 is T; 863 is T; 864 is G; 1016 is G, or any combination thereof. More specifically, with respect to part c), the invention provides a nucleotide sequence substantially identical to SEQ ID NO:7, and having a modified nucleotide sequence selected from nucleotide 389 is G and 390 is A (SEQ ID NO:5); nucleotide 437 is T, 438 is G and 439 is G (SEQ ID NO:6); 470 is C and 472 is T; 476 is T, 477 is G, and 478 is T; 689 is G, 690 is A and 691 is G; 728 is T, 729 is A, and 730 is T; 863 is T and 864 is G; 1016 is G, or any combination thereof. [emphasis added]

[0271] Examples of a variant phytase polynucleotide of the invention also include a polynucleotide that encodes a polypeptide having substantially as set forth in SEQ ID NO:8, but having an W68E, Q84W, A95P, K97C, S168E, R181Y, N226C, Y277D or any combination thereof and retain phytase activity. [emphasis added]

Accordingly, the phytase SEQ ID NO:2 is a wild-type *E. coli* B phytase and SEQ ID NO:10 is a "man-made" phytase of this invention whose parent sequence is – the *E. coli* K12 phytase SEQ ID NO:8.

In light of the instant amendment and these remarks, Applicants respectfully submit that the rejection under the written description requirement of section 112, first paragraph, can be properly withdrawn.

Issues under 35 U.S.C. §112, first paragraph, enablement requirement

The rejection of claims 1, 2, 20 to 22, 51, and 53 to 62 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement is maintained, and claims 11, 12 and 66 are newly rejected, for reasons set forth in paragraphs 21 to 24, pages 8 to 9, of the OA.

The Office does note that the specification is enabling for a method to recombinantly produce the polypeptide of the invention SEQ ID NO:10. However, it is alleged that the specification does not provide reasonable enablement to recombinantly produce any phytase. See e.g., paragraph 21, first sentence, on page 8, of the OA.

Thus, it appears that the Office is not questioning whether "nucleic acids isolated from a wild type *E. coli* bacterium" are sufficiently enabled by the specification. The Office is concerned that the pending wording of the claims might read on recombinant expression of any phytases – not just "nucleic acids isolated from a wild type *E. coli* bacterium". For example, "nucleic acids isolated from a recombinant *E. coli* bacterium" might encompass any phytase (see, e.g., lines 5 to 8, of paragraph 20, page 7; and the sentence spanning pages 8 to 9, of the OA).

The instant amendment addresses this issue, thus satisfying the Examiner's concerns. The instant amendment clarifies that the claimed methods of the invention only recombinantly express "nucleic acids isolated from a wild type *E. coli* bacterium", or non-natural or synthetic forms thereof, or the novel phytase SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9) first described in this invention.

Also, please note Applicants' comments above regarding the phytase SEQ ID NO:2, which is a wild-type *E. coli* B phytase, and SEQ ID NO:10, which is a "man-made" phytase of this invention.

In light of the instant amendment and these remarks, Applicants respectfully submit that the rejection under the enablement requirement of section 112, first paragraph, can be properly withdrawn.

Issues Under 35 U.S.C. § 102(e)

Claims 1, 2, 20 to 22, 51, and 53 to 62 remain rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Berka *et al.*, U.S. Patent No. 5,866,118, issued February 2, 1999, and filed March 18, 1997 (hereinafter "Berka"). The filing date of the earliest priority document for this application is August 13, 1997 (for USSN 08/910,798).

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. In re Paulson, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994)(citing In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131; pg 2100-76, 8th ed., Rev. 3, August 2005.

As noted by the Office, Berka discloses cloning and recombinant expression of a phytase from the filamentous fungus *Thennomyces lanuginosus*. After entry of the instant amendment, claimed methods of this invention will be limited to recombinant expression of "nucleic acids isolated from a wild type *E. coli* bacterium", or non-natural or synthetic forms thereof, or the novel phytase SEQ ID NO:10 (encoded, e.g., by SEQ ID NO:9) first described in this invention.

Accordingly, because Berka is not a single prior source which contains each and every limitation of the claimed invention, the rejection under section 102 can be properly withdrawn.

Issues Under 35 U.S.C. § 103(a)

Claims 1, 2, 11, 12, 20 to 22, 51, 53 to 62 and 66, are newly rejected as allegedly unpatentable over Ostanin, et al., (1992) J. Biol. Chem. 267(32):22830-22836 (hereafter "Ostanin") in view of Berka.

The Office notes Ostanin teaches, *inter alia*, the recombinant production of the protein encoded by the *E. coli* app A gene, a protein having a phytase activity (see, e.g., lines 14 to 15, of paragraph 32, page 11, of the OA). The Office also states that Ostanin is defective in that it does not teach production of the *E. coli* app A gene in yeast.

Berka is cited to cure this defect in Ostanin. However, as acknowledged by the Office, Berka does not teach the production of a naturally-occurring *E. coli* phytase (see, e.g., line 12 to 13, of paragraph 32, page 11, of the OA). Accordingly, because Berka cannot be used to cure the defect in Ostanin, Ostanin in view of Berka does not teach or suggest the (amended) claimed invention, and the rejection under section 103 of Ostanin in view of Berka can be properly withdrawn.

CONCLUSION

In their earlier response, Applicants elected the invention of Group IV, traversed the group restriction requirement, and set forth distinct and specific errors in the restriction requirement and reasons for the Patent Office to reconsider and withdraw, in part, the restriction requirement. Applicants respectfully requested that the claims of Group IV and Group III be rejoined to a generic elected group encompassing claims 1 and 2. Applicants have also requested that the restriction requirement with respect to all the SEQ ID NO:s (the nucleic acid and polypeptide sequences) be withdrawn and treated as a species election under the procedure set forth in MPEP 809.02(a). Accordingly, Applicants have preserved their right to petition the restriction to the Group Director under 37 CFR §1.144; see also MPEP §818.03(c); pg 800-60, 8th Edition, rev. 3, Aug. 2005. Applicants will defer submission of the petition (which can be deferred until allowance of the claims).

It is believed that after entry of the instant amendment and consideration of the remarks set forth herein, the objections to the claims and rejection of the claims under 35 U.S.C. §112, first and second paragraphs, 35 U.S.C. §102(e) and 35 U.S.C. §103(a) can be properly withdrawn, and all claims pending in this application after entry of the instant amendment will be in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

In the unlikely event that the transmittal form is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing **docket No. 564462001824**. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858.720.5133.

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Respectfully submitted,

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